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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,313	02/12/2008	Waltraud Bueb	33613-US-PCT(62106.00023)	9232

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
08/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/597,313	BUEB ET AL.
	Examiner	Art Unit
	TIGABU KASSA	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 17-19, 27, and 29 drawn to a spontaneously dispersible pharmaceutical composition comprising a 5- aryl-4(R)-arylcarbonylamino-pent-2-enoic acid amide substance P antagonist.

Group II, claim(s) 20-24, 28, and 30-32, drawn to a pharmaceutical composition comprising (4R)-4-[N'-methyl-N'-(3,5- bistrifluoro-methyl-benzoyl)amino]-4-(3,4-dichlorobenzyl)-but-2-enoic acid N-[(R)-epsilon- caprolactam-3-yl]-amide as active agent and a carrier medium comprising a lipophilic component and a surfactant, said composition being in an form that is suitable for oral administration.

Group III, claim(s) 25-26, drawn to a spontaneously dispersible pharmaceutical composition as claimed in claim 18 that comprises about 0.05 to about 20% by weight of (4R)-4-[N'-methyl-N'-(3,5- bistrifluoro-methyl-benzoyl)amino]-4-(3,4-dichlorobenzyl)-but-2-enoic acid N-[(R)-epsilon-caprolactam-3-yl]-amide, about 5 to about 85 % by weight of a lipophilic component, about 5 to about 90 % by weight of a surfactant, all weights based on the total composition.

Group IV, claim(s) 33, drawn to a method of treating a subject suffering from a disorder treatable with a 5- aryl-4(R)-arylcarbonylamino-pent-2-enoic acid amide substance P antagonist comprising administering to that subject a therapeutically effective amount of a pharmaceutical composition as claimed in claim 17.

Group V, claim(s) 34, drawn to a process for preparing a spontaneously dispersible pharmaceutical composition containing a 5-aryl-4(R)-arylcarbonylamino-pent-2-enoic acid amide

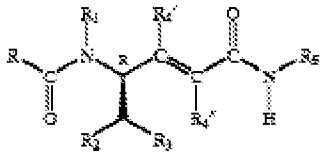
substance P antagonist as an active agent, which process comprises bringing the active agent and a carrier medium comprising a lipophilic component and a surfactant into intimate admixture.

Group VI, claim(s) 35, drawn to a process for the preparing a microemulsion containing a 5-aryl-4(R)- arylcarbonyl-amino-pent-2-enoic acid amide substance P antagonist as an active agent, which process comprises the steps of: (i) bringing the active agent and a carrier comprising (1) a lipophilic component, (2) a surfactant, and 13) a hydrophilic component into intimate admixture to form a spontaneously dispersible pharmaceutical composition; and(ii) diluting the spontaneously dispersible pharmaceutical composition in an aqueous medium to form the microemulsion.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 17 lacks novelty over the teachings of Gerspacher (US Patent No. 6319917, IDS reference). Gerspacher discloses in the abstract as follows:

Compounds of formula I

(I)



wherein R_1, R_2–R_5, R_4', R_4'' and R_5 are as defined in the description, have valuable pharmaceutical properties and are effective especially as NK1 and NK2 antagonists. They are prepared in a manner known per se.

Gerspacher discloses on column 3, lines 28-53 that the compounds of formula I are effective especially as antagonists of NK1 receptors. Their action on that class of receptors and their action on related receptor systems, for example NK2, render the compounds of formula I therapeutically useful in the prevention, the treatment or the diagnosis of a number of diseases, for example diseases of the upper and lower respiratory tract, for example bronchial asthma, allergic asthma, etc. **As already mentioned, the compounds of formula I act as antagonists of substance P** (column 3, lines 34-35). The invention relates likewise to pharmaceutical compositions comprising a compound I or a pharmaceutically

acceptable salt thereof as active ingredient, and to processes for the manufacture thereof (column 9, lines 3-6). Those pharmaceutical compositions are compositions for enteral, such as oral and also rectal, administration, for parenteral administration, for local administration and especially for administration by inhalation to warm-blooded animals, especially human beings, the compositions comprising the pharmacological active ingredient alone or together with customary pharmaceutical excipients (column 9, lines 6-13). It must be noticed that Gerspacher also discloses that it is also possible to prepare (4R)-4-[N'-methyl-N'-(3.5-bistrifluoromethyl-benzoyl)-amino]-4-(3, 4-dichlorobenzyl)-but-2-enoic acid N-[(R)-epsilon-caprolactam-3-yl]-amide which is the structure recited in claims 20 and 25. Because claim 17 lacks inventive step, the remaining claims lack the same or corresponding special technical feature and as such, lack unity. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

2. This application contains claims directed to more than one alternative embodiment (species) of the generic invention. These alternative embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The alternative embodiments (species) are as follows:

a. A single species of P-antagonist (claims 17 and 33-35 are generic; claim 19 recites the species). It must be noticed that the examiner is requesting a single known compound not a subgenus structure.

b. A single species of lipophilic component and a single surfactant (claim 18, 20, 25, and 34-35 are generic; claims 22-23 recite species). It must be noticed that the examiner is requesting a single known compound not a subgenus structure for each of them.

c. A single species of a hydrophilic component (claim 21, 26, and 35 are generic; claim 24 recites species). It must be noticed that the examiner is requesting a single known active not a subgenus structure.

d. A single species of the form of composition (claims 17, 20, 25, and 33-35 are generic; claims 27-32 recite the species).

The alternative embodiments do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the

following reasons: the alternative embodiments represent functionally distinct uses and different structures and lack unity of invention as lacking novelty in light of the teachings of Gerspacher described above.

Applicant is required, in reply to this action, to elect a single alternative embodiment (species) from Group (a) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected alternative embodiment, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of alternative embodiments or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or alternative embodiments may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims

to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on 571-272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 8/03/11

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647